BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0093; FRL–8890–8]

Amides, C_5-C_9, N-[3-(dimethylamino)propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino)propyl]; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of amides, C_5-C_9, N-[3-(dimethylamino) propyl]; (CAS Reg. No. 1044764-00-2) and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl]; (CAS Reg. No. 1044764-06-8) when used as inert ingredients (surfactants) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. Monsanto Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of amides, C_5-C_9, N-[3-(dimethylamino) propyl]; (CAS Reg. No. 1044764-00-2) and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl]; (CAS Reg. No. 1044764-06-8)**.**

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with

the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2011–0093. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Deirdre Sunderland, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 603–0851; e-mail address: *sunderland.deirdre@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*. To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2011–0093 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0093, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation

(8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Exemption

In the **Federal Register** of March 29, 2011 (76 FR 17374) (FRL–8867–4), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 0E7815) by Monsanto Company, 1300 I Street NW., Suite 450 East, Washington DC 20005. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of amides, C_5-C_9, N-[3-(dimethylamino) propyl]; (CAS Reg. No. 1044764-00-2) and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl]; (CAS Reg. No. 1044764-06-8) when used as an inert ingredient (surfactants) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. That notice referenced a summary of the petition prepared by Monsanto Company, the petitioner, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified

cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in

conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] as well as the no-observed-adverse-effect-level (NOAEL)

and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Acute studies revealed low oral and dermal toxicity (OPPTS Harmonized Test Guidelines 870.1100 and 870.1200). When tested on rabbits, the chemical was shown to be mildly irritating to the skin and severely irritating to the eyes (OPPTS 870.2500 and 870.2400). Skin sensitization studies in guinea pigs showed that amides, C_5-C_9, N-[3-(dimethylamino) propyl] was not a skin sensitizer (OPPTS 870.2600).

Several repeat dose studies were conducted on amides, C_5-C_9, N-[3-(dimethylamino) propyl] (OPPTS 870.3050 and 870.3700). A 28-day range finding study on rats showed no evidence of toxicity at doses up to 300 milligrams/kilograms/day (mg/kg/day). Systemic toxicity (e.g., lower body weight gain, food consumption, and effects on red blood cells) were noted at 800 and 1,000 mg/kg/day. Females in the 800 mg/kg/day group also had lower organ weights of the liver, spleen, and thymus.

A second range finding study administered the test substance to female rats on gestation days 6-19. All females in the 1,000 mg/kg/day group were found dead or euthanized *in extremis* by gestation day 8. In the 500 mg/kg/day group, two females were euthanized *in extremis*. Females in this group exhibited clinical signs of toxicity (e.g., rales, increased respiration, gasping, dilated pupils, salivation, and body weight gains). There were no test-substance related clinical findings noted up to150 mg/kg/day. Intrauterine growth and survival were unaffected at dose levels up to 500 mg/kg/day. No external malformations or developmental variations were noted in this study. The maternal and developmental NOAELs for this study were 150 and 500 mg/kg/day, respectively.

A dietary combined 90-day/Reproductive and Developmental Toxicity Screening study in rats did not show evidence of toxicity at exposures up to 175 mg/kg/day (OPPTS 870.3650/3100). At the high-dose (600 mg/kg/day), systemic toxicity was exhibited by clinical findings, lower mean body weights, body weight gains, and food consumption for males, toxicology phase females, and reproductive phase females. Lower ovary, uterus, and pituitary weights were noted for the 600 mg/kg/day reproductive phase females. In addition, lower litter size, number of pups born, implantation sites, and mean pup body weights were noted in the 600 mg/kg/day group in the presence of excessive maternal toxicity. Therefore, the systemic, reproductive, and developmental NOAELs were considered to be 175 mg/kg/day.

No carcinogenicity studies are available for the inert ingredients amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl]. The Agency used a qualitative structure activity relationship (SAR) database (i.e., DEREK Version 11) to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts were identified for the parent nor its potential major metabolite dimethylaminopropylamine (DMAPA). Based on these results and the negative findings in both the mutagenicity (OPPTS 870.5100) and clastogenicity (OPPTS 870.5395) studies along with the lack of evidence of specific target organ toxicity, the Agency concluded that these inert ingredients have low potential to be carcinogenic.

Functional observational battery (home cage, handling, open field, neuromuscular, and physiological observations) and locomotor activity (no remarkable shifts in the pattern of habituation) were recorded for Sprague-Dawley rats treated with 600 mg/kg/day of the test substance and no test-related effects were observed. Although

possible evidence of neurotoxicity was observed in the OPPTS 870.3700 study at 500 mg/kg/day (dilated pupils) and 1,000 mg/kg/day (dilated pupils and clonic convulsions) these clinical signs were considered to be due to generalized toxicity and not of neurologic origin. The Point of Departure (POD) of 175 mg/kg/day used in this risk assessment is protective of the effects seen at these dose levels.

The proposed primary route of metabolism is believed to generate DMAPA which is marketed as an inert ingredient in pesticide formulations. DMAPA (as an inert) has been recently evaluated by the Agency and an exemption from tolerance under 40 CFR 180.920 and 180.930 was established.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological PODs and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the

general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

The POD used in the risk assessment for short-term, intermediate-term, and chronic routes of exposure (i.e., oral, dermal, and inhalation) was from the OPPTS Harmonized Test Guideline 870.3650 toxicity study in rats. The NOAEL is 175 mg/kg/day and the LOAEL is 600 mg/kg/day based on body weight decreases and food consumption for both sexes and lower absolute and relative-to-brain ovary, uterus, and pituitary weights for the reproductive phase females. A 100 fold uncertainty factor was used for the chronic exposure (10X interspecies extrapolation, 10X for intraspecies variability and 1X Food Quality Protection Act (FQPA) factor).

The residential, occupational, and aggregate level of concern (LOC) is for MOEs that are less than 100 and is based on 10X interspecies extrapolation, 10X for intraspecies variability and 1X FQPA factor.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl], EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] in food as follows:

The I-Dietary Exposure Evaluation Model (DEEM) is a highly conservative model with the assumption that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation between the active and inert ingredient (if

any) and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient. The model assumes 100 percent crop treated (PCT) for all crops (every food eaten by a person each day has tolerance-level residues).

2. *Dietary exposure from drinking water***.** For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl], a conservative drinking water concentration value of 100 parts per billion based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure***.** The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

These inerts may potentially be added to pesticide formulations that are used around the home (i.e., fungicides/insecticides/herbicides). Although there are no known or anticipated residential uses for these inert ingredients, in order to be protective of any future uses, a screening level exposure assessment was performed using high-end exposure scenarios for outdoor residential uses. The Agency selected representative scenarios, based on end-use product application methods and labeled application rates.

The mixer/loader/applicator high exposure outdoor scenarios evaluated were Liquid products: Low Pressure Handwand; Liquid products: Hose End Sprayer; and Ready to Use (RTU): Trigger Pump Sprayer Applications.

The Agency believes that the handler scenarios assessed represent worse-case exposures and risks resulting from the use of outdoor pesticide products containing these inert ingredients in residential environments.

Post application high end outdoor residential exposures (i.e., Dermal exposure to treated lawns (adults/children), Hand-to-Mouth activity for toddlers on treated lawns (children), Object-to-Mouth activity for toddlers on treated lawns (children), and Soil ingestion from treated soil (children)) were also evaluated.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] to share a common mechanism of toxicity with any other substances. Amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] may produce the metabolite DMAPA. The toxicity of this metabolite is addressed in the database. For the purposes of this tolerance action, therefore, EPA has assumed that amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. Reproductive and developmental effects were evaluated in a 90-day study conducted on Sprague-Dawley (CD) rats. No evidence of toxicity was noted at exposure levels of 15, 50, and 175 mg/kg/day. Systemic toxicity including lower mean body weights, body weight gains, and food consumption for both sexes and lower absolute and relative-to-brain ovary, uterus, and pituitary weights for the reproductive phase females was exhibited at 600 mg/kg/day. In addition, lower mean live litter size on PND 0, number of pups born and implantation sites, and lower mean pup weights were noted in the 600 mg/kg/day group. Therefore, the systemic, reproductive, and developmental NOAELs are considered to be 175 mg/kg/day. All reproductive and developmental effects were noted in the presence of excessive maternal toxicity; therefore, there was no evidence of increased susceptibility in infants and children.

In addition, an Organization for Economic Cooperation and Development (OECD) 421 reproduction and developmental toxicity screening test using the metabolite dimethylaminopropylamine in Sprague-Dawley rats resulted in parental toxicity at 200

mg/kg/day based on decreased body weight gain and clinical signs (respiratory sounds and piloerection). Reproductive and developmental toxicity were not observed at any dose level.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] is adequate for assessing the sensitivity to infants and children .

ii. There is no indication that amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] are neurotoxic chemicals and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. Although possible evidence of neurotoxicity was observed in OPPTS 870.3700 as indicated in the 500 mg/kg/day group (dilated pupils) and the 1,000 mg/kg/day group (dilated pupils and clonic convulsions), these clinical signs were considered to be due to generalized toxicity and not of neurologic origin.

iii. There is no evidence that amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] results in increased susceptibility in *in utero* rats.

iv. There are no residual uncertainties identified in the exposure databases. The food and drinking water assessment is not likely to underestimate exposure to any subpopulation, including those comprised of infants and children. The food exposure assessments are considered to be highly conservative as they are based on the use of the

highest tolerance level from the surrogate pesticides for every food and 100 PCT is assumed for all crops. EPA also made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] in drinking water. EPA used similarly conservative assumptions to assess post application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl].

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] are not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] from food and water will utilize 35.7 percent of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are currently no known residential uses for amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl]. Since there are no current or proposed residential uses, chronic exposure is not expected; however, inert ingredients are used in a variety of formulations and have the

potential to be used in residential products. A screening level assessment was conducted for residential exposure and the risk was below the Agency level of concern.

Although there is a potential for amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] to produce the metabolite dimethylaminopropylamine (DMAPA), which is currently approved under 40 CFR 180.920 and 180.930, EPA does not anticipate any risk concerns from aggregate exposure to DMAPA for the following reasons:

i. Evidence from toxicology studies indicates that metabolization of amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl], to DMAPA does not occur in significant amounts. The parent chemicals (i.e., amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl]) have a larger and more complete toxicity database which resulted in a higher no observed adverse effect level (NOAEL) than the metabolite, DMAPA. The POD NOAEL selected for all exposure scenarios for amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] is 175 mg/kg/day versus the NOAEL of 50 mg/kg/day for DMAPA. If DMAPA is a major metabolite of amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] then the toxicity endpoints for amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] and DMAPA would be comparable.

ii. The previous risk assessment of metabolite DMAPA (as inert ingredient) indicates that any marginal increase in DMAPA exposure as a result of the use of amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl]

would not alter the DMAPA risk significantly nor change EPA's conclusion regarding the safety of DMAPA. [**Federal Register** August 5, 2009 (74 FR 38924) (FRL–8430–2)]

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] have the potential to be used as inert ingredients in pesticide products that are registered for use**s** that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl].

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and proposed high-end residential exposure scenarios result in aggregate MOEs greater than 100. Because EPA's level of concern for amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk***.** Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). **A**mides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] have the potential to be used as an inert ingredients in pesticide products that are registered for use**s** that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term

residential exposures to amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl].

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and proposed high-end residential exposure scenarios result in aggregate MOEs greater than 100. Because EPA's level of concern for amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in various mutagenicity studies, the lack of a target organ in any of the toxicity studies conducted, and the lack of structural alerts suggestive of carcinogenicity in the structural activity database DEREK Version 11, amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] are not expected to pose a cancer risk to humans.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to amides, C_5-C_9, N-[3-(dimethylamino) propyl] and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl] residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for amides, C_5-C_9, N-[3-(dimethylamino) propyl] or amides, C_6-C_{12}, N-[3-(dimethylamino) propyl].

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180. 910 for amides, C_5-C_9, N-[3-(dimethylamino) propyl]; (CAS Reg. No 1044764-00-2) and amides, C_6-C_{12}, N-[3-(dimethylamino) propyl]; (CAS Reg. No. 1044764-06-8) when used as inert ingredients (surfactants) in pesticide formulations applied pre-and post-harvest.

VII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review

under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*., nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined

that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq*., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 18, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.910, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.910 Inert ingredients used pre-and post-harvest; exemptions from the requirement of a tolerance.

*** * * * ***

Inert ingredients	Limits	Uses
* * *	*	* * *
Amides, C_5-C_9, N-[3-(dimethylamino) propyl]; CAS Reg. No. 1044764-00-2		Surfactant
Amides, C_6-C_{12}, N-[3-(dimethylamino) propyl]; CAS Reg. No. 1044764-06-8		Surfactant
* * *	*	* * *

[FR Doc. 2011-28643 Filed 11/08/2011 at 8:45 am; Publication Date: 11/09/2011]